Electronic Batch Records:

Speaking The Same Language

Maybe you know the painting by Pieter Breughel that portrays the Tower of Babel. Brueghel used the Colosseum in Rome as his model for the giant tower. The biblical story painted by Brueghel tells how the builders, when they began this project, all spoke the same language and understood one another. They had to abandon their vain plans, however, when God punished the people. Suddenly they spoke different languages and no longer understood each other. A chaotic situation arose, a 'Babylonian confusion of tongues'.

We're all well aware that the success of a project stands or falls with speaking the same language and understanding our partners in conversation. But that isn't so easy to accomplish. How do you make sure that you understand each other better, so that breakdowns in communication occur less often, thus ensuring that fewer mistakes are made and that you produce more successful project results faster?

ISA standards can help in developing standard reports. By *Bianca Scholten*

Looking For A Central EBR System

Imagine you work for a large international pharmaceutical company that is currently using paper batch records. Management has given you the task to investigate if it is possible to have one standard system for electronic batch records on its sites in three different countries. Having one central system would lead to advantages like reuse of project effort and knowledge and an improved possibility to compare reports from different sites. And having an electronic system would lead to advantages such as central access to data in real time, avoidance of human errors due to data transcription, faster batch release, etc. The task that you have been given is quite a challenge. Before you can realise all these advantages, you will encounter several difficulties.

You wonder if it is possible to use the same system on three sites, because the sites have different processes, different automation systems, and people may even speak different languages. You will need the help of IT, engineers, production personnel, QA and QC in order to define the user requirements for this new system. When you discuss the problem with them, they appear to have different views on the situation, and they also use different terminology. When you compare the batch records of each site, they seem to contain different kinds of information, they don't have the same structure, and they use different

terminology and different units of measure. What on earth are you going to do to solve this problem?

A few years ago employees of Abbott in the Netherlands found themselves in this difficult situation. Sonja de Heij (QA) told me: "We're using ISA-95 for our EBR project. We're investigating whether we want to implement electronic batch records, and we need to present a proposal in early June so it can be included in the schedule for 2006."

Karst van der Pol (IT) said: "Last year, we started making an IT roadmap with our sister companies. Electronic batch records was an important topic there. We want to achieve systems harmony. EBR was given the highest priority at that time. In particular, the enormous mountain of paper that all quality systems entail is a thorn in our plant manager's side."

How Can Standards Help?

I told the Abbott employees how industrial standards can help solve these kinds of problems. Communicating about a system can be difficult, because different people in the same conversation often assign different meanings to general terms. Standards define words that you can use to discuss the specific problem domain. ISA standards place this terminology within models, which make clear the relationships among the various terms.

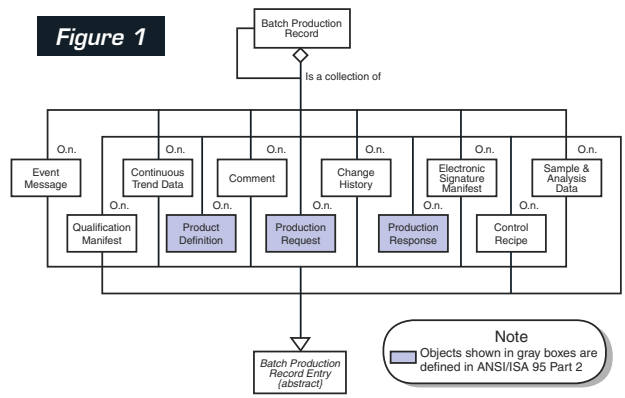
You can compare this principle with drawing a blueprint for a house. A blueprint depicts what the house will look like, with symbols for windows, doors, walls, and roofs. The words Window, Door, Wall, and Roof are familiar to all of us, and we use them to talk to each other about the house. Every house is different, and still we can depict and describe every house with the same symbols and words for doors, roofs, walls, and windows. The same applies to the ISA standards. No two manufacturing companies are alike, and yet you can use the ISA models and terminology to talk with others about the problem domain, like safety (ISA-84), batch control (ISA-88), or enterprise-control system integration (ISA-95).

ISA-88.04: Batch Production Records

When developing a system for electronic batch records, ISA-88 Part 4 provides meaningful help. This standard is about batch production records. It standardises the information within batch production records. **Figure 1** is the basic Batch Production Record model. Within the standard, you will find more detailed models for each object within this figure. The standard also provide tables that define the attributes for each object. For instance: attributes of the object Batch Production Record, are: ID, Description, Creation Date, Last Changed Date, etc. ISA-88.04 is very well suited for the pharmaceutical industry.

It takes into account FDA regulations and 21 CFR Part 11 requirements (Electronic Signatures). As a result it has become easier not only on the level of human communication, but also on the technical level, to define requirements and to develop standard systems for electronic batch records.

Figure 1



ISA-95.03: Activity Models Of Manufacturing Operations Management

Another standard that can help when you specify the requirements for a system for electronic batch records, is Part 3 of ISA-95. This part makes clear what kind of activities take place within a manufacturing company.

On a high level it also explains which information flows between the activities. You can use it to develop a standard approach to discuss activities within the production department, within the lab, etc. I developed such a standard approach for my company, including interview templates.

With our ISA-95 B2M (Business to Manufacturing) analysis we help companies to specify their user requirements, to describe the 'as is' situation and compare different sites. It also leads to a structured description of the future situation and a roadmap to realise this situation. This approach can be applied to many different kinds of industries.

Johnson & Johnson applied it to describe and compare the current situation of their sites in Belgium, Switzerland, Italy, Ireland and the USA. Abbott was one of the first companies that got acquainted with this approach, in their electronic batch record project. I asked Karst van der Pol what he thinks of the approach: "If you asked us: 'Would you do it again?' The answer is 'Yes!' This is something you have to go through. We wrestled with the question, 'What do you put where?' Now we're making an internal translation and we're looking at what something was called before, and what we should call it now using ISA-95 terms."

More information about how to apply the ISA-95 standard can be found in the book 'The Road to Integration; a Guide to Applying the ISA-95 Standard in Manufacturing', by Bianca Scholten. This book is available at www.ISA.org.

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